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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/019,348	02/05/98	GEORGOPOULOS K	MIT-7422

000959
LAHIVE & COCKFIELD
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BOSTON MA 02109

HM22/0624

EXAMINER	
LUBET, M	

ART UNIT	PAPER NUMBER
1644	8

DATE MAILED: 06/24/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/019,348	Applicant(s) Georgopoulos et al.
	Examiner Lubet	Group Art Unit 1644

☒ Responsive to communication(s) filed on *Mar 31, 1999* .

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *1* month(s), ~~or thirty days~~, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-42* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims *1-42* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

APPLICATION NUMBER:09/019,348
ART UNIT: 1644

P lease Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-305-3704. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Paula Hutzell, Supervisory Patent Examiner at Paula Hutzell s@uspto.gov. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

1. Restriction to one of the following inventions is required under 35 U.S.C. 121

I. Claims 1-2, drawn to Aiolos polypeptide, classified in class 514 subclass 12.

II. Claims 4-7, drawn to nucleic acids encoding Aiolos polypeptide, hosts and vectors comprising the same and a method of using the nucleic acids to make proteins, classified in class 435, subclass 320.1 and class 536, subclass 23.5.

III. Claims 3, drawn to antibodies specific to Aiolos polypeptide, classified in class 530, subclasses 387.9 and 388.23.

IV. Claim 8, drawn to a method of making Aiolos polypeptide, classified in class 435, subclass 69.1.

V. Claim 9, drawn to a method of treating an animal by administering an Aiolos polypeptide, classified in class 514, subclass 12.

VI. Claim 9 drawn to a method of treating an animal by administering a cell selected for expression of a product of the Aiolos gene, classified in class 435, subclass 435.

VII. Claim 9 drawn to a method of treating an animal by administering a nucleic acid encoding an Aiolos peptide, classified in class 514, subclass 44.

VIII. Claim 10, drawn to a method of determining is a subject is at risk for a disorder by determining the expression of Aiolos gene classified in class 435 subclasses 6 7.1 and 7.24.

IX. Claim 11, drawn to transgenic animal having Aiolos transgene classified in class 800, subclass 21.

X. Claim 12, drawn to a dimer which includes Aiolos polypeptide and an Ikaros polypeptide, classified in class 514, subclass 350.

XI. Claims 13 and 14 , drawn to a method of providing a proliferation-deregulated cell by causing a cell to misexpress the Aiolos gene classified in class 435, subclass 440.

XII. Claim 15, drawn to a method of culturing an Aiolos-misexpressing cell by introducing the cell into a mammal and culturing the cell classified in class 435, subclass 325

XIII. Claim 16, drawn to a method of reconstituting an immune system by introducing into the mammal an immune system component from a donor mammal which is Aiolos misexpressing classified in class 435, subclass 326

XIV. Claim 17, drawn to a reaction mixture comprising an immune system component and a target tissue, classified in class 435, subclass 325.

XV. Claims 18-28 and 42, a method of providing an antibody comprising providing a

mammal having a cell which is Aiolos deregulated, classified in class 435, subclass 328.

XVI. Claims 29-42, a method of providing an antibody comprising providing a mammal having a cell which is Aiolos null or under expressing mutations at the Aiolos locus, classified in class 435, subclass 323.

2. The inventions are distinct, each from the other because of the following reasons:

The polypeptides of Group I are patentably distinct chemical species from the nuclei acids of Group II, although related as the nucleic acids encode the proteins. The polypeptides can be made without recourse to the nucleic acids by the materially distinct process of biochemical purification from natural sources, and the nucleic acids have separate utility as probes for screening libraries.

The proteins of Group I are patentably distinct chemical species from the antibody of Group III, although related as the antibody can bind the protein. The antibody can cross-react with other proteins. The protein can be made without recourse to the antibody by biochemical purification from natural sources.

Inventions I and Groups V- VII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the polypeptide can be used to elicit antibodies to the polypeptide.

The methods of Groups V -VII, XI-XIII and XV-XVI are patentably distinct. The inventions of Groups V -VII, XI-XIII and XV-XVI are materially different processes and are practiced with materially different products. They are patentable over one another.

The antibodies of Group III are patentably distinct from the nucleic acids of Group II, although related as the antibodies may be raised against proteins encoded by the nucleic acids. The inventions have distinct chemical compositions and distinct functions. The nucleic acids are not required to make the antibodies, which may be raised against proteins made without recombinant expression. The nucleic acids have separate utility as probes, for example.

Invention IX is patentably distinct from the invention of Group I-II, through related as the transgenic animal expresses the Aiolos polypeptide and the gene encoding the Aiolos polypeptide. The Aiolos polypeptide can be made without recourse to the transgenic animal and the gene encoding the Aiolos polypeptide have separate utility as probes for screening libraries.

The Invention of Group X is are patentably distinct chemical species from the invention of

Group I .

3. Because these inventions are distinct for the reasons given above and the researches required for Groups I-XVI are not coextensive, restriction for examination purposes as indicated is proper.

4. After the election of one of the inventions of Groups I-XVI, ed, a further election of species is required and the following requirement shall apply:

Applicant is required under 35 U.S.C. 121 to elect a single disclosed embodiment of the Invention for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, 1-42 are generic.

An example of a specific disclosed embodiment of Invention III is an antibody specific for SEQ ID NO:1.

An example of a specific disclosed embodiment of Invention XII, is a method of reconstituting an immune system by introducing into a mammal a B cell expressing a particular Aiolos misexpressing cell (IE Aio-7-/-).

After election of a specific embodiment of the elected invention, Applicant is required to point out by page and line number, support for the elected species.

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the

inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h)

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Martha Lubet in Art Unit 1816 whose telephone number is (703) 305-7148. The examiner can normally be reached on Monday through Friday from 8:15 AM to 4:45 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at (703) 305-7939. The FAX number for this group is (703) 305-7939. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Martha T. Lubet

TC

THOMAS M. CUNNINGHAM
PRIMARY EXAMINER
GROUP 1800

RESTRICTION ELECTION FACSIMILE TRANSMISSION

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IN COMPLIANCE WITH 1096 OG 30, THE FILING DATE ACCORDED EACH OFFICIAL FAX TRANSMISSION WILL BE DETERMINED BY THE FAX MACHINE DATE STAMP FOUND ON THE LAST PAGE OF THE TRANSMISSION, UNLESS THAT DATE IS A SATURDAY, SUNDAY, OR FEDERAL HOLIDAY WITHIN THE DISTRICT OF COLUMBIA, IN WHICH CASE THE OFFICIAL DATE OF RECEIPT WILL BE THE NEXT BUSINESS DAY.